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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,563

10/24/2003

Michael Draper

16534-526002US

9127

30623

7590

03/01/2011

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

03/01/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,563	DRAPER ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Non Final Office Action

Claims 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 are pending. No claim is allowed. Amendments in claims are entered. Amendments in specification filed on 6/4/2009 are not entered.

Summary of the Office Action

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. Rejection under 35 U.S.C. 103 (a)
5. Double Patenting Rejections
6. Response to Remarks
7. Communication

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Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications and Issued US Patents

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See *Dayco Products Inc. v. Total Containment Inc.*, 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

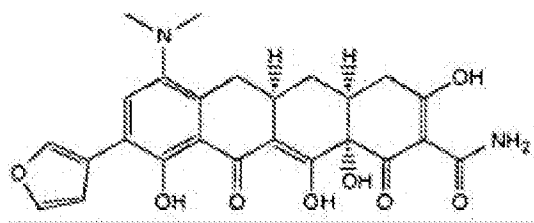
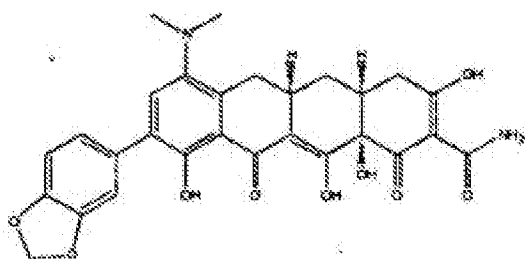
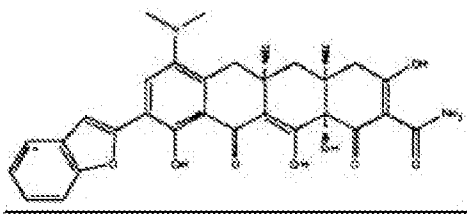
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

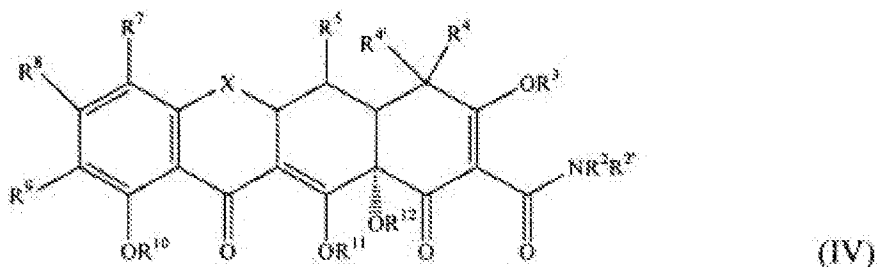
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 rejected under 35 U.S.C.

103(a) as being unpatentable over U.S.C. 103(a) as being unpatentable over Nelson et al. (US Patent 7,056,902). See the entire document especially claims and examples. The reference teaches that these compounds are useful for the treatment of malaria (lines 15-26 on page 119 in original specification). Compounds of claim 11, column 587 and 588 in US '902.



Claim of US 7056,902 (claim 1)



wherein:

X is $\text{CHC}(\text{R}^{13}\text{Y}^*\text{Y})$, or $\text{CR}^{16}\text{R}^{16}$;

R^2 , R^3 , and R^{10} are each hydrogen, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, aryl, heterocyclic, heteroaromatic or a pro-drug moiety ester or amide;

R^7 and R^{11} are each alkyl;

R^4 and R^{12} are each independently alkyl, alkenyl, alkynyl, aryl, hydroxyl, alkoxy, halogen, hydrogen, or taken together to form the oxygen of a carbonyl;

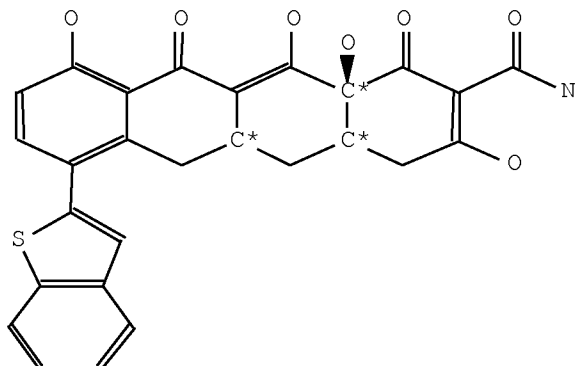
R^{13} , R^{14} , R^{15} , R^{16} and R^{17} are each hydrogen or a pro-drug moiety ester or amide;

R^5 is hydroxyl, hydrogen, thiol, alkanoyl, aroyl, alkaroyl, aryl, heteroaromatic, alkyl, alkenyl, alkynyl, alkoxy, alkylthio, alkylsulfinyl, alkylsulfonyl, alkylamino, arylalkyl, alkyl carbonyloxy, or aryl carbonyloxy;

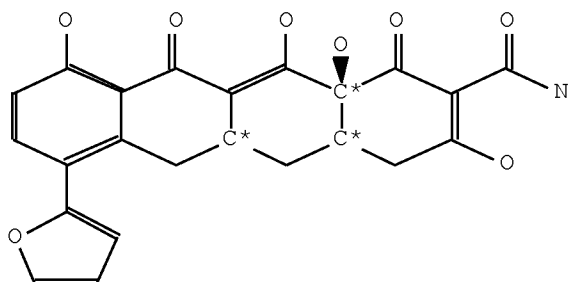
CN.S 7-Benzo[b]thiophen-2-yl-3,10,12,12a-tetrahydroxy-1,11-dioxo-
1,4,4a,5,5a,6,11,12a-octahydro-naphthacene-2-carboxylic acid amide
SDCN RABHLR

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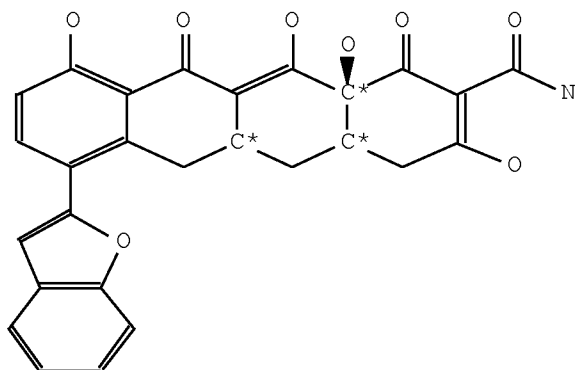
AN.S DCR-768036
CN.S 7-Furan-2-yl-3,10,12,12a-tetrahydroxy-1,11-dioxo-1,4,4a,5,5a,6,11,12a-
octahydro-naphthacene-2-carboxylic acid amide
SDCN RABHLU



AN.S DCR-768862
CN.S 7-Benzofuran-2-yl-3,10,12,12a-tetrahydroxy-1,11-dioxo-
1,4,4a,5,5a,6,11,12a-
octahydro-naphthacene-2-carboxylic acid amide
SDCN RABI9B

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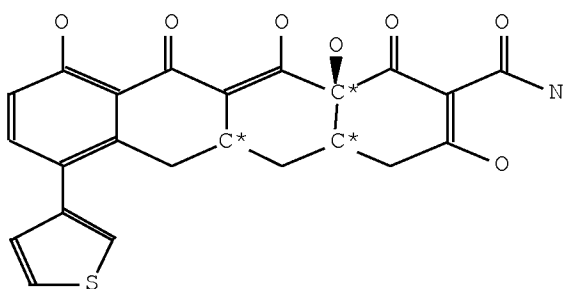
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AN.S DCR-768884

CN.S 3,10,12,12a-Tetrahydroxy-1,11-dioxo-7-thiophen-3-yl-1,4,4a,5,5a,6,11,12a-octahydro-naphthacene-2-carboxylic acid amide

SDCN RABI9X



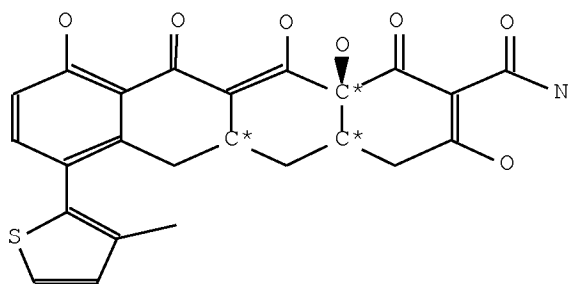
AN.S DCR-768885

CN.S 3,10,12,12a-Tetrahydroxy-7-(3-methyl-thiophen-2-yl)-1,11-dioxo-

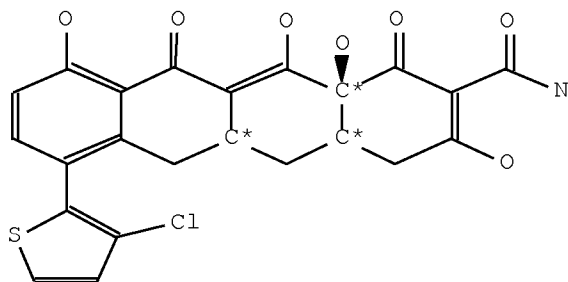
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1,4,4a,5,5a,6,11,12a-octahydro-naphthacene-2-carboxylic acid amide
SDCN RABI9Y



AN.S DCR-768907
CN.S 7-(3-Chloro-thiophen-2-yl)-3,10,12,12a-tetrahydroxy-1,11-dioxo-
1,4,4a,5,5a,6,11,12a-octahydro-naphthacene-2-carboxylic acid amide
SDCN RABIAL



3.

Instant claims differ from the reference in that they are of different generic scope. Presently claimed **invention is the selection of the prior art compounds.**

In present application claims are now limited to furanyl-----

It had been decided by Courts that the indiscriminate selection of “some” from among “many” is considered prima facie obvious. In re Lemin, 141 USPQ 814 (1964); National Distillers and Chem. Corp. V. Brenner, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed tetracycline compounds from the genus in the reference for the treatment of malaria since such compounds would have been suggested by the reference as a whole useful for the treatment of malaria. It had been decided by the court that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169

USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have obvious to one skilled in the art.

4. Claims 81 and 82 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/19784 and US Patent 7,045,507/WO 02/072031.
5. WO 01/19784 teaches compositions of structurally similar tetracycline which embraces Applicants claimed invention. See the entire document especially the abstract, formula on page 9 and substituents on page 10, examples and claims.
6. US Patent 7,045,507/WO 02-072031 teaches the compositions of structurally similar presently claimed tetracycline compounds. See the entire document especially compounds of formula (I) on page 2 and page 6, examples and claims in WO publication.

Instant claims differ from the reference in that they are of different generic scope. The compositions as presently claimed have been taught by the cited references. It has been decided by the court that even in a case where the reference does not teach the same use of the composition, the two different intended uses are

not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

It had been decided by Courts that the indiscriminate selection of “some” from among “many” is considered *prima facie* obvious. *In re Lemin*, 141 USPQ 814 (1964); *National Distillers and Chem. Corp. V. Brenner*, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed compounds would have been suggested to one skilled in the art.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within the genus. *In re Susi*, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the *Federal Circuit in Merck & Co. V. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have obvious to one skilled in the art.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 4, 29-36, 42-43, 49-62, 66-82 and 84-85 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/490,867.

Although the conflicting claims are not identical, they are not patentably distinct from each other because R9 in copending application can be hydrogen and R7 can be aminoalkyl, alkylamino, aryl or heterocyclic moiety which has been claimed in the present application. Therefore, presently claimed invention is considered obvious to the claimed subject matter of the above co-pending application.

2. Claims of the present invention are generically taught by the prior art and are considered obvious for the reasons cited above.

Claims 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/039,230 (see claims 1, 32-35, 37-47), 11/490,867 and 11/348,608. Although the conflicting claims are not identical, they are not patentably distinct from each other because each encompasses 9-aminomethyl tetracycline compounds as defined by the instant claims. Presently claimed invention is broad and covers the compounds of the cited co-pending application when R₉ represents alkylamino group. However, the claimed compounds and/or the 9-aminomethyl groups recited by the instant claims are encompassed by the claims of the cited copending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 4, 29-36, 42, 43, 49-62, 66-82, 84 and 85 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. US Patent 7,056,902 (10/337,914). Although the conflicting claims are not identical, they are not patentably distinct from each other

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because claims of the present invention is a selection of the prior art compounds. Claims of the present invention are considered obvious over the US'902 for the reasons cited above.

Response to Remarks

Applicants' response filed on 9/23/10 is hereby acknowledged. Applicant's arguments were fully considered and the response is as follows:

Amendments in Specification

Request to enter the amendments in specification has been considered. No reasons are provided for the amendments. All the amendments should be marked i.e. what is new added which was not in the previously filed application. The amendments are 150 pages long. Applicants must mark the changes they have made in the specification which according to the response was in original application. The amendments are not entered and will be entered when Applicant will submit with marked changes. No new matter should be added.

Obviousness Rejection

Applicant's arguments are found persuasive therefore rejection over method claims is withdrawn over WO 01/19784 and US 7045,507/WO 02/072031 are

withdrawn. However, rejection over composition claims 81 and 82 are maintained. It has been decided by the court that even in a case where the reference does not teach the same use of the composition, the two different intended uses are not distinguishable in terms of the composition, see *In re Thuau*, 57 USPQ 324; *Ex parte Douros*, 163 USPQ 667; and *In re Craige*, 89 USPQ 393.

Double Patenting Rejections

Terminal disclaimer has been filed on US Patent 7,595,309 (10/853,635) therefore double patenting rejection is withdrawn.

Applicants arguments are fully considered and were found persuasive therefore DP rejection over 10/996,119 is withdrawn.

Appellant argues that the instant applicant was filed on 10/24/2003 after the filing of copending applications 11/490,867; 11/039,230 (see claims 1, 32-35, 37-47); 11/348,608 and 11/490,867. Since present applications are not allowable the rejection is maintained (MPEP 804).

10/921,580 is abandoned therefore rejection is withdrawn.

The rejection on 12/351,309 is withdrawn as it appears there is an inadvertent typing error.

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Arguments are found persuasive therefore rejection over 10/943,571 is withdrawn.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612

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